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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,046

09/16/2003

Scott E. Miller

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04/17/2007

Timothy J. Oyer, Ph.D.
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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/664,046	Applicant(s) MILLER ET AL.	
	Examiner Nathan A. Bowers	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15-23, 25-31, 33-35, 41-44, 46-50, 53 and 73-82 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 15-23, 25-31, 33 and 73-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34, 35, 41-44, 46-50, 53, 81 and 82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>102306, 011706, 042505, 011805</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group II, claims 34, 35, 41-44, 46-50, 53, 81 and 82 in the reply filed on 06 February 2007 is acknowledged. The traversal is on the grounds that a single search covering all claims would not place an undue burden on the Examiner. This is not found persuasive because the groups are drawn to two separate sensing systems comprising different components.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9, 15-23, 25-31, 33 and 73-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06 February 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 41 is dependent on claim 40, which is a canceled claim. It is understood that claim 41 should be rewritten as dependent on claim 34.

Claim 48 recites the limitation "the actuator" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 34, 35, 43, 44, 46, 47, 59, 50, 53, 81 and 82 are rejected under 35 U.S.C. 102(e) as being anticipated by Freeman (US 6653124).

With respect to claims 34, 35 and 44, Freeman discloses an apparatus comprising a device having a predetermined reaction site (Figure 2:12) having a volume of less than 1 milliliter. This is described in column 1, lines 41-52 and in column 23, line 61 to column 24, line 48. Although Freeman does not describe the exact volume of the reactors, Freeman does indicate in column 1, lines 23-31 and throughout the reference that microfluidic bioreactors capable of accommodating nanoliter and microliter scale quantities are well known in the art.

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Column 24, lines 25-28 and column 29, lines 46-50 indicate that the apparatus comprises dissolved oxygen and pH measuring devices.

With respect to claim 43, Freeman discloses the apparatus in claim 34 wherein a plurality of reactors (12) are present. This is apparent from Figures 1 and 2.

With respect to claims 46 and 81, Freeman discloses the apparatus in claim 34 wherein at least one surface of the predetermined reaction site comprises a polymer. Column 16, line 44 to column 17, line 30 indicates that polymer and copolymer adhesive layers are added to the microchambers. Column 10, lines 39-50 state that the surfaces of the reaction area are coated with proteins to facilitate cell binding. Column 14, lines 20-32 state that the reaction sites are constructed from polyesters and/or polyethylenes.

With respect to claims 47 and 82, Freeman discloses the apparatus in claim 34 wherein the living cell is either a mammalian or insect cell. The apparatus of Freeman is fully capable of culturing these cell types. Throughout the reference, Freeman describes drug testing by providing cell-based screening, so it can safely be assumed that the device is especially geared towards the culture of human tissue cells.

With respect to claims 49, 50 and 53, Freeman discloses the apparatus in as previously described above. In addition, Freeman teaches in column 29, lines 46-50 that it is known in the art to monitor temperature during cell culturing procedures.

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2) Claims 34, 35, 44, 46, 47, 49, 50, 53 and 82 are rejected under 35

U.S.C. 102(e) as being anticipated by Sheppard Jr. (US 6143247).

With respect to claims 34, 35 and 44, Sheppard Jr. discloses an apparatus comprising a device having a predetermined reaction site (Figure 2:24) characterized by a volume of less than 1 milliliter. This is described in column 35, line 22 to column 36, line 22. Column 15, lines 48-55 teach that the volume of the reaction site ranges from 5 to 1,000 microliters. Column 18, lines 18-30 state that the device includes various detectors, sensors, temperature control elements, and control systems. Specifically, the use of pH and dissolved gas sensors when culturing cells is considered to be well known in the art.

With respect to claim 46, Sheppard Jr. discloses the apparatus in claim 34 wherein at least one surface of the predetermined reaction site comprises a polymer. Column 18, lines 31-65 state that the reaction area includes proteins and antibodies capable of binding to cultured cells.

With respect to claims 47 and 82, Sheppard Jr. discloses the apparatus in claim 34 wherein the living cell is either a mammalian or insect cell. Sheppard Jr. specifically discloses the use of mammalian cells in column 18, lines 31-36. the apparatus is considered fully capable of accommodating insect cells.

With respect to claims 49, 50 and 53, Sheppard Jr. discloses the apparatus in as previously described above. In addition, Sheppard Jr. teaches in column 25, lines 37-67 that it is known in the art to monitor temperature during cell culturing procedures.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3) Claims 41, 42 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Freeman (US 6653124) or Sheppard Jr. (US 6143247) each as applied to claim 34, and further in view of Kapur (US 6548263).

Freeman and Sheppard Jr. disclose the apparatus set forth in claim 34 as set forth in the 35 U.S.C. 102 rejections above. Both references teach the use of sensors and detectors, and therefore imply that a control system is utilized for regulating system parameters. Freeman and Sheppard Jr., however, do not expressly disclose the use of a processor for managing data obtained by the sensors.

Kapur discloses a microfluidic substrate for culturing and screening cells. Column 7, lines 63-67, column 26, lines 1-5, and column 39, line 60 to column 40, line 25 state that a controller, sensors, and associated actuators are provided for regulating temperature, oxygen content, and carbon dioxide content during cellular growth.

Freeman, Sheppard Jr. and Kapur are analogous art because they are from the same field of endeavor regarding microfluidic cell culture systems.

At the time of the invention, it would have been obvious to ensure that the microfermenters of Freeman and Sheppard Jr. were in communication with control systems capable of regulating dissolved oxygen content, pH, and temperature. Freeman and Sheppard Jr. both indicate that the use of sensors capable of determining various environmental factors is well known in the bioreactor art. By providing an linked control system, one would have been able

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to monitor and manage the bioreactor automatically, and thereby increase the efficiency of the operation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34, 35, 43, 44, 49, 50 and 53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 79-82 and 92-100 of copending Application No. 10/664067.

The claims of copending Application No. 10/664067 disclose an apparatus comprising a reaction site having a volume of less than 500 microliters. The claims further describe the use of temperature, pH, glucose, pressure, and

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optical density sensors. The instant application is generic to copending Application No. 10/664067 because copending Application No. 10/664067 discloses additional features such as a membrane dividing the reaction site.

This is a provisional obviousness-type double patenting rejection.

Claims 34, 35, 43, 44, 49, 50 and 53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 70, 100, 101, 103 and 104 of copending Application No. 10/927789.

The claims of copending Application No. 10/927789 disclose an apparatus comprising a reaction site having a volume of less than 500 microliters. The claims further describe the use of temperature, pH and oxygen sensors. The instant application is generic to copending Application No. 10/927789 because copending Application No. 10/927789 discloses additional limitations regarding rotation of the chip about an axis.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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